EXHIBIT 2

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, *ex rel.* JULIE LONG, *Relators,* v. JANSSEN BIOTECH, INC., *Defendant.*	Civil Action No. 16-CV-12182-FDS

DEFENDANT JANSSEN BIOTECH, INC.'S SUPPLEMENTAL OBJECTIONS AND RESPONSES TO RELATOR-RELATOR JULIE LONG'S INTERROGATORY NOS. 3, 5, 7, 8, 9, 15, 20, and 22

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, and pursuant to the March 9, 2023 Order of Magistrate Judge M. Page Kelley (ECF No. 375), Defendant Janssen Biotech, Inc. ("Janssen" or "Defendant") hereby submits these supplemental responses and objections to Relator's Interrogatory Nos. 3, 5, 7, 8, 9, 15, 20, and 22 as follows.

Janssen has not asserted and does not intend to assert the advice of counsel defense. For avoidance of doubt, by providing the requested factual information and the identities of the individuals who provided privileged legal advice, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided, it is not asserting the advice of counsel defense and has not waived, and it has no intention of waiving, any applicable privilege. Janssen reserves the right to recall from discovery any inadvertently produced document that is protected by the attorney-client privilege, the work product immunity, or any other applicable privilege or immunity. If privileged documents are inadvertently produced, Janssen does not waive or intend to waive any privilege pertaining to such documents, or to any other information or documents.

Janssen's Supplemental Objections and Responses to Relator's Interrogatories are based on Janssen's current information and belief as a result of reasonable searches and inquiries, which are ongoing as necessary. Consistent with Fed. R. Civ. P. 26 and 33, no response or partial response contained herein is to be construed as precluding Janssen from further developing or investigating contentions, facts, documents, or any other matter which is the subject of Relator's Interrogatories, or from modifying or supplementing its responses accordingly. This is consistent with the positon Relator has taken in her recent responses to Janssen's Interrogatories. *See* Relator's Supplemental Objections and Responses to Janssen's Interrogatory Nos. 6–8 (March 17, 2023) ("Relator also objects on the ground that the interrogatory is premature because discovery is ongoing and is only in the initial stages and Relator has not yet completed her pretrial investigation, discovery, or preparation of her case for trial.").

Janssen's Supplemental Objections and Responses are in addition to and do not waive any objections as to competence, authenticity, relevance, materiality, propriety, privilege, admissibility, and any and all other objections and grounds which would or could require or permit the exclusion of any document or statement therein from evidence. All such objections and grounds are reserved and may be interposed at any time prior to or at the time of trial.

Janssen has constrained its Supplemental Objections and Responses to the Interrogatories below to the scope defined by the Court's order on phased discovery dated December 14, 2020 ("Phased Discovery Order"). Janssen reserves the right to make further objections to any of Relator's Interrogatories should the Court-ordered scope of discovery change. By objecting now, Janssen does not waive any future objections that might be applicable.

GENERAL OBJECTIONS

Janssen makes each of the following general objections, which it incorporates in its responses to each of the Interrogatories:

1. Janssen objects to the Interrogatories as untimely under the Court's order dated December 18, 2020, which required written discovery requests to be served by January 22, 2021.

2. Janssen further objects to Relator's Interrogatories as in violation of Local Rule 26.1(c) and the Court's order dated December 18, 2020, both of which limit each party to 25 interrogatories. Relator served 18 enumerated interrogatories on January 19, 2021, which Relator amended per Court order on May 14, 2021; 1 enumerated interrogatory on May 13, 2021; 14 enumerated interrogatories on May 19, 2021; and 3 enumerated interrogatories on January 3, 2022, bringing her total number of interrogatories to 36. When factoring in subparts of Relator's Interrogatories and Amended Interrogatories, which per the Federal Rules of Civil Procedure should be counted independently, Relator has served, and Defendant has responded to, at least 77 Interrogatories. Fed. R. Civ. P. 33(a)(1) ("Unless otherwise stipulated or ordered by the court, a party may serve on any other party no more than 25 written interrogatories, *including all discrete subparts*.") (emphasis added); *Security Ins. Co. of Hartford v. Trustmark Ins. Co.*, No. 3:01CV2198 (PCD), 2003 WL 22326563, at *1 (D. Conn. Mar. 7, 2003) ("A subpart is discrete and therefore regarded as a separate interrogatory when it is logically or factually independent of the question posed by the basic interrogatory."); *Myers v. U.S. Paint Co., Div. of Grow Grp.*, 116 F.R.D. 165, 165 (D. Mass. 1987) (The Court can "strike a set of interrogatories in which subparts are utilized merely for the purpose of evading the limit."). When incorporating the subparts to Relator's Definitions and Instructions to her Interrogatories, Relator has served, and Defendant has responded to, over 600 Interrogatories.

3. Janssen's inquiry and research into the subject matter of this litigation, and the items requested and enumerated in the Interrogatories, are ongoing. Janssen intends to conduct further inquiry and investigation. No response or partial response contained herein is to be construed as precluding Janssen from further developing or investigating contentions, facts, documents, or any other matter which is the subject of these Interrogatories, or from modifying or supplementing its responses accordingly.

4. Janssen objects to the Interrogatories, Definitions, and Instructions to the extent that they seek to impose obligations or requirements on Janssen which are greater than or different from those imposed by the Federal Rules of Civil Procedure and/or any other applicable law, rule, or regulation.

5. Janssen objects to the Interrogatories to the extent they seek documents or information that are neither relevant to the subject matter of this action nor reasonably calculated to lead to the discovery of admissible evidence.

6. Janssen objects to the Interrogatories, Definitions, and Instructions to the extent they are vague, ambiguous, overbroad, or unduly burdensome.

7. Janssen objects to the Interrogatories to the extent they seek documents or information not within the control of Janssen. Janssen's Responses are based on information reasonably available to it, and Janssen will respond to these Interrogatories only on its own behalf.

8. Janssen objects to the Interrogatories to the extent they seek documents or information subject to and protected from disclosure by the attorney-client privilege, the attorney work product doctrine, and/or any other applicable privilege or protection. No written response or production of documents which contains information, opinions, documents, or facts subject to

any privilege or protection, or references to information, opinions, documents, or facts subject to any privilege or protection, is to be construed as a waiver of the attorney-client privilege, the attorney work product doctrine, or any other applicable privilege, protection, or doctrine for any purpose.

9. As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense. For avoidance of doubt, by providing the requested factual information and the identities of the individuals who provided privileged legal advice, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided, it is not asserting the advice of counsel defense and has not waived, and it has no intention of waiving, any applicable privilege. Janssen reserves the right to recall from discovery any inadvertently produced document that is protected by the attorney-client privilege, the work product immunity, or any other applicable privilege or immunity. If privileged documents are inadvertently produced, Janssen does not waive or intend to waive any privilege pertaining to such documents, or to any other information or documents.

10. Janssen objects to the Interrogatories to the extent they seek documents that already have been provided to Relator, are publicly available or otherwise equally available to Relator, or would be more appropriately sought from third parties to whom subpoenas or requests could be directed, or through means that are more convenient, more efficient, more practical, less burdensome, or less expensive.

11. Janssen objects to the Interrogatories to the extent they seek documents or information that would require Janssen to disclose trade secret, proprietary, and/or confidential information, except as provided for in the Protective Order agreed to by the parties.

12. Janssen objects to the Interrogatories to the extent that they incorporate incorrect assertions of fact or law. Janssen's responses are not a concession that any incorporated assertions or conclusions of fact or law are correct.

13. Janssen objects to the Interrogatories to the extent they seek documents or information outside of the scope authorized in the Phased Discovery Order, including to the extent they seek discovery unrelated to support services provided by Relator during her employment as an Area Business Specialist ("ABS") at Janssen to the physician practices specifically alleged in the Second Amended Complaint ("SAC"). *See* 2d Am. Compl. ¶¶ 175–76, 191–93. While Janssen agrees that documents and information beyond the scope authorized by the Court in the Phased Discovery Order may fall within the scope of subsequent discovery, requests for such documents and information are outside of the scope of the Court's guidance for the narrow initial discovery that was to be the subject of Relator's immediate requests. As such, Janssen objects to each Interrogatory to the extent that it seeks documents or information beyond the scope of the Phased Discovery Order.

14. Janssen objects to the definitions in Relator's Instruction 3(a), (i), (*l*), (n), (o), (p), (q), (s), (u) and (w) as vague, ambiguous, overbroad, unduly burdensome, not calculated to lead to the discovery of admissible evidence, and beyond the scope authorized in the Phased Discovery Order.

15. Janssen objects to the definition of "Electronically stored information" or "ESI" in Relator's Instruction 3(k) as overbroad and unduly burdensome. All productions of ESI made by Janssen pursuant to these Interrogatories will be made in accordance with, and subject to the provisions of, the ESI Protocol agreed to by the parties.

16. Janssen objects to the definition of "Employee" in Relator's Instruction 3(i) as overbroad and unduly burdensome.

17. Janssen objects to Relator's Definitions and Instructions, including Relator's Instructions 3(i), 3(*l*), 3(w), and 6, to the extent they seek to impose obligations on entities that are distinct from Janssen, including, but not limited to, Janssen's parents, U.S. and non-U.S. subsidiaries, divisions, affiliates, predecessors, successors, agents, partners, limited partners, and independent contractors. By defining Janssen and "Defendant" to include entities that are distinct from Janssen and not parties to this action, Relator improperly conflates Janssen with distinct entities that are third parties. Therefore, Janssen construes "Janssen," "Defendant," "You," and "Your" to refer only to Janssen and its employees. Janssen will respond to the Interrogatories based on a reasonable inquiry of individuals expected to possess the requested information.

18. Janssen objects to Relator's Instruction 12 to the extent it purports to impose requirements beyond those prescribed by Fed. R. Civ. P. 26(b)(5). Janssen will log requested documents withheld from production as required by Rule 26(b)(5) and in accordance with, and subject to the provisions of, the Protective Order agreed to by the parties.

19. Janssen objects to Relator's Instructions 14(b) and 14(c) to the extent they seek information not reasonably available to Janssen from internal employment records as overbroad, unduly burdensome, not calculated to lead to the discovery of admissible evidence, and beyond the scope authorized in the Phased Discovery Order.

20. Janssen objects to Relator's Interrogatories, Definitions, and Instructions, including Relator's Instruction 8, to the extent they seek information before October 28, 2006 as outside the scope of this phase of discovery under the Phased Discovery Order.

21. Janssen objects to the Interrogatories to the extent they request information that is "not reasonably accessible because of undue burden or cost" under Fed. R. Civ. P. 26(b)(2)(B), including to the extent they request information that is in archived systems, files, or storage.

22. Janssen further objects to any implication that the standard for Janssen's responses to the Interrogatories is any different than the standard Relator must meet when answering Janssen's interrogatories. In particular, Janssen notes that Relator has made the following objections and statements in its Supplemental Objections and Responses to Defendant's Interrogatories 6 to 18, which Janssen incorporates as equally applicable to the Interrogatories:

a. "Plaintiff objects to the Interrogatories to the extent that they seek to force Relator to prematurely adopt or lock into a legal position";

b. "Plaintiff objects to this interrogatory to the extent Janssen seeks to have Relator compile or summarize information contained in the documents that she produced in this action and the burden of deriving or ascertaining the answer will be substantially the same for Relator as it would be for Defendant";

c. "Plaintiff objects to the extent that this interrogatory is requesting that Plaintiff state the evidentiary support for each alleged Anti-Kickback Statute violation, because it is misusing this interrogatory to improperly attempt to obtain a detailed narrative of Plaintiff's case or pretrial memorandum";

d. "Plaintiff also objects on the ground that the interrogatory is premature because discovery is ongoing and is only in the initial stages and Plaintiff has not yet completed her pretrial investigation, discovery, or preparation of her case for trial";

e. "Plaintiff objects on the ground that responding to this interrogatory would be unduly burdensome, and it is not proportional to Defendant's needs during the discovery stage";

f. "Plaintiff will supplement this response and list the evidentiary support for the falsity element of her False Claims Act violation claims after substantial discovery has been completed."

RESPONSES TO INTERROGATORIES 3, 5, 7, 8, 9, 15, 20, and 22

INTERROGATORY NO. 3:

Identify each Employee who reviewed or analyzed the lawfulness of helping physicians open an IOI, including when each Employee performed the review or analysis and the Employee's position at the time of such review or analysis.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 3:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory, to the extent it seeks information that is not related to support services provided by Relator during her employment as an ABS at Janssen to the physician practices specifically alleged in the SAC, as outside the scope of this phase of discovery under the Phased Discovery Order. Janssen further objects to this Interrogatory as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence, particularly to the extent that it requests Janssen to "[i]dentify each Employee" who performed reviews or analysis over a 25-year time period of 1998 to the present, as well as the dates and Employee's position at the time of the reviews and analyses. Janssen further objects to this Interrogatory to the extent that it requests information protected by the attorney-client privilege, attorney work product protection, or any other applicable privilege or protection. Janssen further

objects to this Interrogatory to the extent it purports to require a response prior to the completion of document production and depositions within this phase of discovery.Janssen further objects to the phrase "helping physicians open an IOI." Janssen will interpret this Interrogatory as asking it to identify the people who reviewed or analyzed the lawfulness of the IOI Support Services identified by Relator in her response to Janssen's Interrogatory No. 2.

As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense. In answering Interrogatory No. 3, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided. For avoidance of doubt, by providing the requested factual information and the identities of the individuals who provided privileged legal advice, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided, it is not asserting the advice of counsel defense and has not waived, and it has no intention of waiving, any applicable privilege.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

Janssen had a Health Care Compliance ("HCC") department. As stated in Janssen policy documents, the role of the HCC department was to "[o]versee and monitor[] the implementation of [a] compliance program" and "develop standards of conduct and policies and procedures that promote conformance to the company's compliance program." JANSSENBIO-037-00000270 at 277-282. Janssen has produced relevant and responsive HCC policies and training presentations, including policies related to Entertainment and Business Meals, the promotion of FDA-Regulated Products, and Consulting and Product-Related Items and Services Provided to Customers, which are listed in Appendix A. Janssen has produced versions of these policies dating back to the early 2000s.

Janssen also had a Promotional Review Committee ("PRC"). As stated in Janssen policy documents, the role of the PRC was to "review[] all promotional materials to ensure medical accuracy and regulatory compliance with applicable laws, regulations and guidelines." JANSSENBIO-018-00001322 at 1322. Janssen has produced Standard Operating Procedures for the PRC, which outline the roles of various committee members and the processes underlying the committee's review. For example:

JANSSENBIO-018-00001325	JANSSENBIO-018-00001266	JANSSENBIO-018-00001277
JANSSENBIO-018-00001260	JANSSENBIO-018-00001292	JANSSENBIO-018-00001305
JANSSENBIO-018-00001284	JANSSENBIO-018-00001322	

The PRC included members from various Janssen departments, including HCC Regulatory, HCC Privacy, Legal, and Medical. According to the PRC SOP, the role of the HCC PRC reviewer was to "[e]nsure[] that PRC materials triaged to the HCC PRC reviewer . . . comply with applicable PGHCC&P (Pharmaceutical Group Health Care Compliance & Privacy) policies, procedures and guidelines, J&J and industry standards, and applicable State and Federal laws" and provide appropriate approval. JANSSENBIO-018-00001266 at 1268. According to the PRC SOP, the role of the Legal PRC reviewer was to "[e]nsure[] that PRC reviewed materials comply with applicable state and federal laws and Corporate Policy, including, but not limited to, those related to FDA advertising and promotion, Medicare and Medicaid requirements, Health Care Compliance, False Claims Act, Lanham Act, fraud and abuse laws and product liability." *Id.* at 1269. Membership on the PRC rotated on a frequent basis, and specific individuals who sat on the PRC with respect to the IOI Support Services at issue are listed on the PRC forms produced in this litigation, which are listed in Appendix B.

Janssen attorneys Freddy Jimenez (Assistant General Counsel, September 1999–January 2016), Kathleen Hamill (Assistant General Counsel, Centocor Board, April 2000–2011;

Assistant General Counsel, Regulatory, 2011–present), Chris Guiton (Assistant General Counsel, July 2007–March 2019), and John Vaughan (Senior Counsel, 2007–June 2012) served on the PRC at various times. In addition to the personnel who served on the PRC, Janssen attorneys Michael McCulley (Assistant General Counsel, April 1982–December 2012), Deidre Meehan (Assistant General Counsel, Regulatory, August 2007–December 2020), and Daryl Todd (Senior Counsel, Regulatory, April 2010–June 2015; Assistant General Counsel, Regulatory, June 2015–present) were additional regulatory attorneys within the Immunology department. Janssen also retained outside counsel from Reed Smith, Hogan & Hartson, and Akin Gump.

For convenience, the following list encompasses the Janssen individuals significantly involved in reviewing or analyzing the lawfulness of the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2:

Individual	Title	IOI Support Program
Chris Guiton	Assistant General Counsel (July 2007–Mar. 2019); Senior Director, US State Government Affairs (Mar. 2019–present)	General legal advice regarding Site of Care ("SOC") educational materials, including IOI Support Services, between July 2007 and March 2019. Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services: Infusion Services Review (iBiz); Raising the Infusion Suite Experience (RISE)
Kathleen Hamill	Assistant General Counsel, Centocor Board (Apr. 2000–2011); Assistant General Counsel, Regulatory (2011–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between April 2000 and present. Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:

Individual	Title	IOI Support Program
		Checkpoints for Infusion Center Optimization; Managing Biologics in the Physician Office; Private Payer Contracting Considerations; Successful Infusion Suite Management for Gastroenterology
Freddy Jimenez	Assistant General Counsel (Sept. 1999–Jan. 2016)	General legal advice regarding SOC educational materials, including IOI Support Services, between 1999 and 2016. Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services: Becoming an Alternative Site of Care; Considerations for Proactive Practice Management; Emerging Trends in Healthcare; Infusion Optimization Modeler (IOM); Practice Compliance for Remicade; Private Payer Contracting Considerations for Remicade; Remicade Account Review; Setting Up In-Office Infusions of Remicade
Michael McCulley	Assistant General Counsel (Apr. 1982–Dec. 2012)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2000 and 2012.
Diedre Meehan	Assistant General Counsel, Regulatory (Aug. 2007–Dec. 2020)	General legal advice regarding SOC educational materials, including IOI Support Services, between August 2007 and December 2020.
Daryl Todd	Senior Counsel, Regulatory (Apr. 2010–June 2015); Assistant General Counsel, Regulatory (June 2015–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2010 and present.
John Vaughan	Senior Counsel (2007–June 2012)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2007 and June 2012.

Individual	Title	IOI Support Program
		Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services: Emerging Trends in Healthcare; Enhancing Infusion Efficiency; Infusion Optimization Modeler (IOM); Infusion Therapy Services Provided in Converted ASC Space; IV Therapy: An Important Option for Your Patients (a/k/a Why IV?); Managing Biologics in the Physician Office; Private Payer Contracting Considerations; Successful Implementation of a New Infusion Suite; Successful Implementation of a New Infusion Suite for Gastroenterology Practices; Successful Infusion Suite Management for Gastroenterology

AMENDED INTERROGATORY NO. 5:

Identify the managers and officers who made, or had significant involvement in, your original decision and all subsequent decisions to contract with Xcenda, LLC, including any parent, subsidiary, predecessor, successor, or affiliate, including The Lash Group, LLC, to provide one or more types of IOI Support, including when each manager or officer made, or was involved in, the decision and the manager's or officer's position at the time of such decision.

SUPPLEMENTAL RESPONSE TO AMENDED INTERROGATORY NO. 5:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory, to the extent it seeks information that is not related to support services provided by Relator during her employment as an ABS at Janssen to the physician practices specifically alleged in the SAC, as outside the scope of this phase of discovery under the Phased Discovery Order. Janssen

further objects that this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). "Significant involvement," in particular, is an inherently subjective term, and reasonable minds could differ as to whether a particular person was "significantly" involved in any given activity. This response is based on Janssen's good faith understanding, and it seeks to address Relator's concerns about providing a response that is over-inclusive or under-inclusive. Janssen further objects to this Interrogatory as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence, particularly to the extent that it requests Janssen to identify all managers and officers, across the entire company, who made decisions over a 25-year time period of 1998 to the present, as well as the dates and Employee's position at the time of the decisions. Janssen further objects to this Interrogatory to the extent it purports to require a response prior to the completion of document production and depositions within this phase of discovery.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

The Lash Group, LLC, primarily runs Janssen's online patient and physician assistance portal, through which assistance is offered to patients and healthcare providers regarding insurance and reimbursement. These services include benefits investigations, prior authorization support and monitoring, information on the appeals process, coding and billing information, and an online portal through which these services can be accessed. Janssen objects that these types of services are irrelevant to this action and are explicitly carved out of Relator's SAC and Interrogatories. *See, e.g.*, SAC at 78 n. 14 ("Janssen provides accounts other free services, including assistance with obtaining prior authorizations and insurance coverage for Janssen's

products and financial assistance, that Relator does not allege violate the Federal AKS, State AKS, and/or FCA in this action."); Pl.'s Am. Interrogs. Definitions & Instructions 3(*l*) ("Excluded from this definition [of 'IOI Support'] is any assistance that Defendant provided to IOI accounts with obtaining coverage of Remicade and Simponi ARIA from a patient's insurer or a charity. Also excluded from this definition is any support that Defendant provided to hospitals and patients.").

In Janssen's view, there were no officers who had significant involvement in the original decision and subsequent decisions to contract with Xcenda related to IOI Support Services. Based on Janssen's investigation to date, the people with significant involvement in the original decision and subsequent decisions to contract with Xcenda were (1) Michael Ziskind (Director, Public Payer Policy, Strategy & Marketing, 1998–2006); (2) Janice Babia-Ramos (Manager, Health Economics & Reimbursement, January 2003–January 2005; Senior Manager, Site of Care, February 2005–March 2005; Associate Director, Site of Care, March 2005–May 2005); (3) Tom Nyairo (Associate Product Manager, Care Delivery Strategies, August 2004–November 2006); (4) Ken Gillmer (Senior Product Manager, Site of Care Marketing, June 2006–August 2007; Associate Director, Site of Care, August 2007–October 2008; Director, Site of Care Marketing, October 2008–October 2010); (5) Michael Wolfe (Product Director, Marketing, Site of Care, October 2010–April 2012; Product Director, Rheumatology Marketing, April 2012–April 2016); and (6) Jim Knepp (Product Director, Site of Care, June 2012–October 2015).

There were, of course, other people involved in contracting with Xcenda, but, in Janssen's view, their involvement did not rise to the level of "significant." However, for Relator's convenience, Janssen points to previously produced documents, which provide further information about such individuals. For example:

- On January 1, 2002, Centocor entered into a Master Consulting Agreement with the Lash Group signed by W. Anthony Vernon and Richard A. Bierly. JANSSENBIO-036-0000001. Under this Master Consulting Agreement, Centocor executed numerous work orders.

- On February 25, 2004, Centocor and the Lash Group entered into a Work Order signed by Mike Ziskind. JANSSENBIO-036-00000020.

- On June 3, 2004, Centocor and the Lash Group entered into a Work Order signed by Karen E. Smith. JANSSENBIO-036-00000028.

- On January 1, 2008, Centocor and Xcenda, which had merged with the Lash Group in October 2007, entered into a Work Order signed by Randy McGonigal and Scott Habig. XCE-CID 0000895.

- On December 12, 2008, Centocor and Xcenda entered into a Work Order signed by Peggy Mellody. XCE-CID 0003808.

- On January 1, 2009, Centocor and Xcenda entered into a Work Order signed by Kim Taylor. JANSSENBIO-021-00001544.

Centocor, and later Janssen, continued to engage Xcenda to both develop educational content and to present content to practices. Janssen produced work orders, agreements, and related documents concerning its engagement of Xcenda in production volumes JANSSEN.007, JANSSEN.016, and JANSSEN.018, and at JANSSENBIO-035-00024666 to JANSSENBIO-035-00024917 and JANSSENBIO-036-00000309 to JANSSENBIO-036-00000323.

AMENDED INTERROGATORY NO. 7:

Identify the managers and officers who made, or had significant involvement in, the initial decision that you would provide and the subsequent decisions to continue providing the Infusion Services Review (also known as "IBiz," "Infusion Business Review," "Managing Biologics in the Physician Office," "MBPO," "Account Review," and "Business Review") presentation, program, or consultative session to IOI Accounts (including the Phase 1 Accounts), including when each manager or officer made, or was involved in, the decision and the manager's or officer's position at the time of such decision.

SUPPLEMENTAL RESPONSE TO AMENDED INTERROGATORY NO. 7:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory, to the extent it seeks information that is not related to support services provided by Relator during her employment as an ABS at Janssen to the physician practices specifically alleged in the SAC, as outside the scope of this phase of discovery under the Phased Discovery Order. Janssen further objects that this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, Janssen objects to the use of the terms "Infusion Services Review," "presentation," "program," "consultative session," "significant involvement," and "IOI Accounts." "Significant involvement," in particular, is an inherently subjective term, and reasonable minds could differ as to whether a particular person was "significantly" involved in any given activity. This response is based on Janssen's good faith understanding, and it seeks to address Relator's concerns about providing a response that is over-inclusive or under-inclusive. Janssen further objects to this Interrogatory as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence, particularly to the extent that it requests Janssen to identify all managers and officers, across the entire company, who made decisions over a 25-year time period of 1998 to the present, as well as the dates and Employee's position at the time of the decisions. Janssen further objects to this Interrogatory to the extent it purports to require a response prior to the completion of document production and depositions within this phase of discovery.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

The development and/or approval of the strategy or plan to provide and/or continue to provide the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2 was a function of certain members of the Site of Care team.

In Janssen's view, there were no officers who had significant involvement in the initial decision and the subsequent decisions to provide the Infusion Services Review program. The following people listed as Project Owners on relevant PRC forms had significant involvement in the original decision and subsequent decisions to provide the Infusion Services Review program:

Individual	Title	Infusion Services Review
Janice Babia-Ramos	Manager, Health Economics & Reimbursement (Jan. 2003–Jan. 2005); Senior Manager, Site of Care (Feb. 2005–Mar. 2005); Associate Director, Site of Care (Mar. 2005–May 2005)	Infusion Optimization Modeler (IOM)
Lawrence Conley	Product Manager, Site of Care/Institutional Marketing (Feb. 2013–Oct. 2013); Product Manager, Gastroenterology (Nov. 2013–Apr. 2016)	Infusion Optimization Modeler (IOM); Infusion Services Review (iBiz)
Ken Gillmer	Senior Product Manager, Site of Care Marketing (June 2006–Aug. 2007); Associate Director, Site of Care (Aug. 2007–Oct. 2008); Director, Site of Care Marketing (Oct. 2008–Oct. 2010)	Managing Biologics in the Physician Office
Kendra Heusinkveld	Product Manager, Emerging Stakeholders (Oct. 2015–May 2017)	Infusion Services Review (iBiz)
Hitu Malhotra	Product Manager, Remicade (Sept. 2010–Apr. 2012)	Infusion Optimization Modeler (IOM); Managing Biologics in the Physician Office
Tom Nyairo	Associate Product Manager, Care Delivery Strategies (Aug. 2004–Nov. 2006)	Infusion Optimization Modeler (IOM); Remicade Account Review
Bill Pillat	Product Manager, Site of Care (May 2017–Aug. 2019)	Infusion Services Review (iBiz)
Faiz Sadeq	Product Manager, Alternative Site of Care (Dec. 2010–July 2011);	Managing Biologics in the Physician Office

Individual	Title	Infusion Services Review
	Product Manager, Site of Care/Hospital (July 2011–Dec. 2012)	
Sandra Shpilberg	Product Manager (2002–2005)	Remicade Account Review (Physician Office Account Review for Remicade)
Michael Wolfe	Product Director, Marketing, Site of Care (Oct. 2010–Apr. 2012); Product Director, Rheumatology Marketing (Apr. 2012–Apr. 2016)	Managing Biologics in the Physician Office
Michael Ziskind	Director, Public Payer Policy, Strategy & Marketing (Centocor) (1998-2006)	Managing Biologics in the Physician's Office

The following people on the Site of Care team had significant involvement in the original decision and subsequent decisions to provide the Infusion Services Review program:

Individual	Title	Infusion Services Review
John Arena	Product Manager, Site of Care (May 2009–June 2010); Product Director, Site of Care (July 2010–approx. 2012)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between May 2009 and 2012.
Janice Babia-Ramos	Manager, Health Economics & Reimbursement (Jan. 2003–Jan. 2005); Senior Manager, Site of Care (Feb. 2005–Mar. 2005); Associate Director, Site of Care (Mar. 2005–May 2005)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between January 2003 and May 2005.
Michelle Carrigan	Product Director, Channel Marketing (Nov. 2019–Mar. 2022)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between November 2019 and February 2020.
Lawrence Conley	Product Manager, Site of Care/Institutional Marketing (Feb. 2013–Oct. 2013); Product Manager, Gastroenterology (Nov. 2013–Apr. 2016)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between February 2013 and April 2016.

Individual	Title	Infusion Services Review
Joseph Donahue	Product Manager, Site of Care (May 2006–June 2007)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between May 2006 and June 2007.
Ken Gillmer	Senior Product Manager, Site of Care Marketing (June 2006–Aug. 2007); Associate Director, Site of Care (Aug. 2007–Oct. 2008); Director, Site of Care Marketing (Oct. 2008–Oct. 2010)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between June 2006 and October 2010.
Kendra Heusinkveld	Product Manager, Emerging Stakeholders (Oct. 2015–May 2017)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between October 2015 and May 2017.
Jim Knepp	Product Director, Site of Care (June 2012–October 2015)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between June 2012 and October 2015.
Hitu Malhotra	Product Manager, Remicade (Sept. 2010–Apr. 2012)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between September 2010 and April 2012.
Thao Marzullo	Product Manager, Site of Care Marketing (July 2013–Aug. 2015)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between July 2013 and August 2015.
Tim Michael	Product Director, Site of Care (May 2016–June 2019)	Significantly involved in the SOC strategy and the

Individual	Title	Infusion Services Review
		development of IOI educational materials, including IOI Support Services, in use between May 2016 and June 2019.
Tom Nyairo	Associate Product Manager, Care Delivery Strategies (Aug. 2004–Nov. 2006)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between August 2004 and November 2006.
Randy McGonigal	Senior Director, Site of Care Marketing (Dec. 2002–Jan. 2010)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between December 2002 and January 2010.
Bill Pillat	Product Manager, Site of Care (May 2017–Aug. 2019)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between May 2017 and August 2019.
Faiz Sadeq	Product Manager, Alternative Site of Care (Dec. 2010–July 2011); Product Manager, Site of Care/Hospital (July 2011–Dec. 2012)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between December 2010 and December 2012.
Scott Shelhamer	Regional Business Director (Apr. 2015–Feb. 2020)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between April 2015 and February 2020.
Sandra Shpilberg	Product Manager (2002–2005)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI

Individual	Title	Infusion Services Review
		Support Services, in use between 2002 and 2005.
Karen Trahan	Regional Business Director (2000–2015)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between 2000 and 2015.
Michael Wolfe	Product Director, Marketing, Site of Care (Oct. 2010–Apr. 2012); Product Director, Rheumatology Marketing (Apr. 2012–Apr. 2016)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between October 2010 and April 2016.
David Wright	Group Product Director, Stakeholder (Feb. 2013–Dec. 2014); Group Product Director, Rheumatology, IV/IOI (Dec. 2014–Mar. 2016)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between February 2013 and March 2016.
Michael Ziskind	Director, Public Payer Policy, Strategy & Marketing (Centocor) (1998-2006)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between 1998 and 2006.

AMENDED INTERROGATORY NO. 8:

Identify the Employees (excluding Area Business Specialists and Regional Business Managers) who are or were responsible for reviewing or analyzing the lawfulness of providing the Infusion Services Review (also known as "IBiz," "Infusion Business Review," "Managing Biologics in the Physician Office," "MBPO," "Account Review," and "Business Review") presentation, program, or consultative session to IOI Accounts (including the Phase 1 Accounts), including when each Employee performed the review or analysis and the Employee's position at the time of such review or analysis.

SUPPLEMENTAL RESPONSE TO AMENDED INTERROGATORY NO. 8:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory, to the extent it seeks information that is not related to support services provided by Relator during her employment as an ABS at Janssen to the physician practices specifically alleged in the SAC, as outside the scope of this phase of discovery under the Phased Discovery Order. Janssen further objects that this Interrogatory is vague, ambiguous, and overbroad in its use of the terms "Infusion Services Review," "presentation," "program," "consultative session," and "IOI Accounts." Janssen further objects to this Interrogatory as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence, particularly to the extent that it requests Janssen to identify each Employee other than ABSs and Regional Business Managers ("RBMs") who had authority over reviews or analyses over a 25-year time period of 1998 to the present, as well as the dates and Employee's position at the time of the reviews and analyses. Janssen further objects to this Interrogatory to the extent it purports to require a response prior to the completion of document production and depositions within this phase of discovery.

As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense. In answering Interrogatory No. 8, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided. For avoidance of doubt, by providing the requested factual information regarding the identities of the individuals who provided privileged legal advice, Janssen is not asserting the advice of counsel defense and has not waived, and has no intention of waiving, any applicable privilege.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

Given the substantial overlap in subject matter, Janssen incorporates its response to Interrogatory No. 3.

Janssen attorneys Freddy Jimenez (Assistant General Counsel, September 1999–January 2016), Kathleen Hamill (Assistant General Counsel, Centocor Board, April 2000–2011; Assistant General Counsel, Regulatory, 2011–present), Chris Guiton (Assistant General Counsel, July 2007–March 2019), and John Vaughan (Senior Counsel, 2007–June 2012) served on the PRC at various times. In addition to the personnel who served on the PRC, Janssen attorneys Michael McCulley (Assistant General Counsel, April 1982–December 2012), Deidre Meehan (Assistant General Counsel, Regulatory, August 2007–December 2020), and Daryl Todd (Senior Counsel, Regulatory, April 2010–June 2015; Assistant General Counsel, Regulatory, June 2015–present) were additional regulatory attorneys within the Immunology department. Janssen also retained outside counsel from Reed Smith, Hogan & Hartson, and Akin Gump.

The following list encompasses the Janssen individuals significantly involved in reviewing or analyzing the lawfulness of the Infusion Services Review programs:

Individual	Title	IOI Support Program
Chris Guiton	Assistant General Counsel (July 2007–Mar. 2019); Senior Director, US State Government Affairs (Mar. 2019–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between July 2007 and March 2019. Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services: Infusion Services Review (iBiz); Raising the Infusion Suite Experience (RISE)
Kathleen Hamill	Assistant General Counsel, Centocor Board (Apr. 2000–2011), Assistant General Counsel, Regulatory (2011–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between April 2000 and present.

Individual	Title	IOI Support Program
		Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services: Checkpoints for Infusion Center Optimization; Managing Biologics in the Physician Office; Private Payer Contracting Considerations; Successful Infusion Suite Management for Gastroenterology
Freddy Jimenez	Assistant General Counsel (Sept. 1999–Jan. 2016)	General legal advice regarding SOC educational materials, including IOI Support Services, between 1999 and 2016. Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services: Becoming an Alternative Site of Care; Considerations for Proactive Practice Management; Emerging Trends in Healthcare; Infusion Optimization Modeler (IOM); Practice Compliance for Remicade; Private Payer Contracting Considerations for Remicade; Remicade Account Review; Setting Up In-Office Infusions of Remicade
Michael McCulley	Assistant General Counsel (Apr. 1982–Dec. 2012)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2000 and 2012.
Diedre Meehan	Assistant General Counsel, Regulatory (Aug. 2007–Dec. 2020)	General legal advice regarding SOC educational materials, including IOI Support Services, between August 2007 and December 2020.
Daryl Todd	Senior Counsel, Regulatory (Apr. 2010–June 2015); Assistant General Counsel, Regulatory (June 2015–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2010 and present.
John Vaughan	Senior Counsel (2007–June 2012)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2007 and June 2012.

Individual	Title	IOI Support Program
		Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services: Emerging Trends in Healthcare; Enhancing Infusion Efficiency; Infusion Optimization Modeler (IOM); Infusion Therapy Services Provided in Converted ASC Space; IV Therapy: An Important Option for Your Patients (a/k/a Why IV?); Managing Biologics in the Physician Office; Private Payer Contracting Considerations; Successful Implementation of a New Infusion Suite; Successful Implementation of a New Infusion Suite for Gastroenterology Practices; Successful Infusion Suite Management for Gastroenterology

AMENDED INTERROGATORY NO. 9:

Identify the Employees (excluding Area Business Specialists and Regional Business Managers) who are or were responsible for reviewing or analyzing the impact or effect that providing the Infusion Services Review (also known as "IBiz," "Infusion Business Review," "Managing Biologics in the Physician Office," "MBPO," "Account Review," and "Business Review") presentation, program, or consultative session had on Remicade and/or Simponi ARIA sales and utilization at IOI Accounts, including when each Employee performed the review or analysis and the Employee's position at the time of such review or analysis.

SUPPLEMENTAL RESPONSE TO AMENDED INTERROGATORY NO. 9:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory, to the extent it seeks information that is not related to support services provided by Relator during her employment as an ABS at Janssen to the physician practices specifically alleged in the SAC,

as outside the scope of this phase of discovery under the Phased Discovery Order. Janssen further objects that this Interrogatory is vague, ambiguous, and overbroad in its use of the terms "impact," "effect," "Infusion Services Review," "presentation," "program," "consultative session," "sales," "utilization," and "IOI Accounts." Janssen further objects to this Interrogatory as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence, particularly to the extent that it requests Janssen to identify each Employee other than ABSs and RBMs who had authority over reviews or analyses over a 25-year time period of 1998 to the present, as well as the dates and Employee's position at the time of the reviews and analyses. Janssen further objects to this Interrogatory to the extent it purports to require a response prior to the completion of document production and depositions within this phase of discovery.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

No persons are or were responsible for reviewing or analyzing the impact or effect that providing the Infusion Services Review program had on Remicade and/or Simponi ARIA sales and utilization at IOI Accounts.

AMENDED INTERROGATORY NO. 15:

State all the facts that you believe support your contention in Affirmative Defense No. 13 of your Answer to the Second Amended Complaint that "Janssen reasonably interpreted the statutes and regulations at issue in the SAC," including identifying all persons who performed the analyses that form the basis for Affirmative Defense No. 13 and when such analyses were performed.

SUPPLEMENTAL RESPONSE TO AMENDED INTERROGATORY NO. 15:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory, to the extent it seeks information that is not related to support services provided by Relator during her employment as an ABS at Janssen to the physician practices specifically alleged in the SAC, as outside the scope of this phase of discovery under the Phased Discovery Order. Janssen further objects to this Interrogatory on the ground that the request for "all" facts and witnesses related to Janssen's theories of defense is vague and ambiguous, overly broad, and unduly burdensome. *See generally* Wright & Miller, Fed. Prac. & Proc. Civ. § 2167 (3d ed.) ("Contention interrogatories may be held unduly broad if they ask in an undifferentiated way for 'all' facts or witnesses that support an opposing party's case.").

Janssen further objects to this Interrogatory to the extent that it requests information protected by the attorney-client privilege, attorney work product protection, or any other applicable privilege or protection.

Janssen also objects to any implication that the reasonableness of its interpretation of the statutes and regulations at issue in the SAC can only be supported by contemporaneous, affirmative analyses that were performed at a particular time.

Janssen also objects that the statutes and regulations at issue in this matter speak for themselves. Janssen further objects that this Interrogatory improperly calls for a legal conclusion, which is not permitted by Federal Rule 33. *See Martin v. Evans*, No. 16-CV-11362-PBS, 2018 WL 10247394, at *3 (D. Mass. Feb. 6, 2018); *Iantosa v. Benistar Admin Servs., Inc.*, No. 08-11785-NMG, 2012 WL 220224, at *3 (D. Mass. Jan. 24, 2012).

Janssen also objects to this Interrogatory on the ground that it is premature. As Relator has acknowledged in her own interrogatory responses, discovery is in the initial stages and remains ongoing. *See* Relator's Supplemental Objections and Responses to Janssen's

Interrogatory Nos. 6–8 (March 17, 2023). Consistent with Fed. R. Civ. P. 26 and 33, Janssen will suplement its response to this Interrogatory as necessary.

Janssen also objects to this Interrogatory to the extent it purports to require a response prior to the production by Relator of documents and information relevant to the subject of this Interrogatory, including all documents that Relator provided to or receives from the federal and state governments in connection with this case. Janssen objects to providing a response to this Interrogatory unless and until Relator completes production of documents and/or other information responsive to Janssen's discovery requests. Moreover, Janssen has not received complete responses to its subpoenas to government agencies. Janssen objects to providing a response to this Interrogatory unless and until the government agencies complete their production of documents.

As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense. In answering Interrogatory No. 15, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided. For avoidance of doubt, by providing the requested factual information and the identities of the individuals who provided privileged legal advice, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided, it is not asserting the advice of counsel defense and has not waived, and it has no intention of waiving, any applicable privilege.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

It is objectively reasonable to conclude that the provision of the IOI Support Services did not violate the Anti-Kickback Statute, and therefore there was no violation of the False Claims Act. The reasonableness of Janssen's interpretation of governing statutes and regulations is supported by the text of the Anti-Kickback Statute and False Claims Act, the relevant case law,

and publicly available guidance materials from HHS, which have consistently confirmed that product support services do not constitute unlawful kickbacks unless they provide substantial and independent value to the prescriber. *See* 68 Fed. Reg. 23,731, 23,735 (May 5, 2003); *see also, e.g.*, Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202, 79,210 (Dec. 27, 2013). Moreover, the IOI Support Services at issue here were not an "inducement," and there can be no violation of the Anti-Kickback Statute without an "inducement." Furthermore, on multiple occasions, HHS-OIG has found that the Anti-Kickback Statute is not implicated by comparable product support programs and services. *See, e.g.*, OIG Advisory Opinions and judicial decisions cited in Janssen's Motion to Dismiss, ECF No. 59, at 6, 8-12. These materials and the underlying statutes and regulations speak for themselves.

Janssen further responds that the reasonableness of its interpretation of the governing statutes and regulations is supported by the robust practices and standards of its HCC department applicable to ABS engagement with physician practices. As stated in Janssen policy documents, the role of the HCC department was to "[o]versee and monitor[] the implementation of [a] compliance program" and "develop standards of conduct and policies and procedures that promote conformance to the company's compliance program." JANSSENBIO-037-00000270 at 277-282.

HCC members who reviewed the IOI Support Services at issue include Chris Zalesky (Director/Executive Director, Marketing Compliance (Centocor), April 1998–October 1999; Director, Regulatory Affairs (Janssen), October 1999–March 2002; Senior Director, Regulatory Affairs (Janssen), March 2002–May 2004; Executive Director, World Wide Office of Health Care Compliance and Policy, June 2004–March 2010; Vice President, Global Policy &

Guidance, 2010–2016), Maripat Rhood (Manager, HCC, May 2001–July 2007), Michael Schoeck (Director, HCC and Privacy, October 2002–August 2008; Director, HCC, August 2008–December 2010), Edmund Greenidge (Director, HCC, 2005–October 2010), Gina Giordano (HCC Officer, June 2009–October 2015), John "Chip" Franz (HCC Officer, October 2010–August 2014), Angela Wood (HCC Officer, November 2010–June 2014), Roger Kung (HCC Officer, 2011–2012), Tom Cornely (HCC Officer, Immunology, April 2013–2016), Michele Blades (HCC Officer, March 2017–present), and Erin Parsons (HCC Officer, January 2015–November 2019).

Janssen has produced relevant and responsive HCC policies and training presentations, including policies related to Entertainment and Business Meals, the promotion of FDA-Regulated Products, and Consulting and Product-Related Items and Services Provided to Customers, which are listed in Appendix A. The HCC policies and trainings are one place that set forth the company's reasonable interpretation of the governing statutes and regulations.

The reasonableness of Janssen's interpretation of the governing statutes and regulations is also supported by the existence and practices of the Promotional Review Committee. *See* Janssen's response to Interrogatory No. 3 for information concerning the role of, and persons with involvement in, the PRC, and the Standard Operating Procedures and PRC forms contained in Appendix B.

As explained in more detail below, the reasonableness of Janssen's interpretation of the governing statutes and regulations is further supported by Janssen's disclosure of its IOI Support Services in connection with a significant federal government investigation that began as early as 2003 and ultimately resulted in the government's declination to intervene in at least two qui tam

suits: *U.S. ex rel. Heineman v. J&J*, No. 2:05-cv-2633 (D.N.J.); *U.S. ex rel. Greer v. J&J d/b/a Centocor*, No. 07-cv-1660 (D. Minn.).

Between approximately 2003 and 2011, the Department of Justice ("DOJ") and the U.S. Department of Health and Human Services Office of Inspector General ("OIG") conducted an investigation that involved, among other topics, the IOI Support Services. On July 2, 2003, the U.S. Attorney's Office for the District of New Jersey issued a document request that included 40 requests for production. *See* JANSSENBIO-037-00001377. On February 11, 2005, the government followed up with 10 additional requests for production. *See* JANSSENBIO-037-00001373. In response to these requests, Janssen produced documents bates labeled JJDOJ0000001-0102780.

Additionally, on November 28, 2005, Janssen received additional document requests from the government. *See* JANSSENBIO-037-00001365. These document requests were focused on sales information and adverse effects of Remicade. *See id.* at Request Nos. 2-4, 7. In response to these requests, Janssen produced documents bates labeled JJDOJ-CIV-000002-216610.

DOJ also requested, and Janssen produced, all documents produced by Janssen in *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 1:01-cv-12257-PBS (D. Mass.) (the "AWP MDL"), totaling over 105,000 pages, in the summer of 2008.

Janssen has produced documents labeled JJDOJ0040284-0065635 in this litigation and intends to, at a minimum, produce responsive documents identified in the ranges labeled JJDOJ0080027-0082953 and JJDOJ0086213-0087503.

As part of this investigation, DOJ and OIG reviewed and analyzed the patient support services that Relator now claims are kickbacks. The government closed the investigation, and

the DOJ and OIG did not take any action against Janssen, despite knowing about the IOI Support Services. Given the government's extensive knowledge of Janssen's IOI Support Services, and the fact that the government has not taken any action against Janssen, Janssen reasonably believed that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the AKS and FCA. Indeed, in many instances, the services Relator claims are kickbacks are either identical or substantially similar to the presentations that the government investigated. *Compare, e.g.*, JANSSENBIO-035-00010006 through JANSSENBIO-035-00010092 at JANSSENBIO-035-00010053 *with* JANSSENBIO-013-00005631; JANSSENBIO-035-00010006 through JANSSENBIO-035-00010092 at JANSSENBIO-035-00010018 *with* JANSSENBIO-017-00025032; JANSSENBIO-035-00008490 *with* JANSSENBIO-014-00002781.

Janssen's reasonable belief that its interpretation of the governing statutes and regulations was reasonable is further supported by the fact that Janssen disclosed and relied on its provision of IOI Support Services in its defense in the AWP MDL, including with live testimony at trial. Examples of such disclosures can be found on the AWP MDL docket at ECF Nos. 1326-7, 1325, 3289, 3288, 3397; *see also* Transcript of Bench Trial - Day Five. Witnesses with knowledge concerning this investigation are Joseph Braunreuther, Freddy Jimenez, and Chris Zalesky.

Janssen's investigation is ongoing. Janssen expressly reserves the right to supplement, amend, and/or correct its response to Amended Interrogatory No. 15 any time in light of any facts, documents, or other information that may subsequently come to light and/or for any other appropriate reason. Janssen's response to Amended Interrogatory No. 15 shall not be deemed to constitute an admission or representation that any statement or characterization herein is complete.

INTERROGATORY NO. 20:

State whether you contend that when you provided each of the various types of IOI Support and IOI Support Programs that you had a good faith belief that your actions did not violate any law, statute, or regulation, and if so set forth all facts, documents, and evidence that support your contention and identify the witnesses who have knowledge concerning your contention.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 20:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory as untimely under the Court's order dated December 18, 2020, which required written discovery requests to be served by January 22, 2021.

Janssen further objects to the Interrogatory as in violation of Local Rule 26.1(c) and the Court's order dated December 18, 2020, both of which limit each party to 25 interrogatories. Relator served 18 enumerated interrogatories on January 19, 2021, which Relator amended per Court order on May 14, 2021; 1 enumerated interrogatory on May 13, 2021; 14 enumerated interrogatories on May 19, 2021; and 3 enumerated interrogatories on January 3, 2022, bringing her total number of interrogatories to 36. When factoring in subparts of Relator's Interrogatories and Amended Interrogatories, which per the Federal Rules of Civil Procedure should be counted independently, Relator has served, and Defendant has responded to, at least 77 Interrogatories. When incorporating the subparts to Relator's Definitions and Instructions to her Interrogatories, Relator has served, and Defendant has responded to, over 600 Interrogatories.

Janssen further objects to this Interrogatory to the extent that it requests information protected by the attorney-client privilege, attorney work product protection, or any other applicable privilege or protection.

Janssen further objects that this Interrogatory is vague, ambiguous, overbroad, and unduly burdensome in its reference to "each of the various types of IOI Support and IOI Support Programs," "any law, statute, or regulation," and "all facts, documents, and evidence." *See generally* Wright & Miller, Fed. Prac. & Proc. Civ. § 2167 (3d ed.) ("Contention interrogatories may be held unduly broad if they ask in an undifferentiated way for 'all' facts or witnesses that support an opposing party's case."). Janssen also objects to this Interrogatory in its entirety as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence.

Janssen also objects to this Interrogatory on the ground that it is premature. As Relator has acknowledged in her own interrogatory responses, discovery is in the initial stages and remains ongoing. Consistent with Fed. R. Civ. P. 26 and 33, Janssen will suplement its response to this interrogatory as necessary.

Janssen further objects that the statutes and regulations at issue in this matter speak for themselves. Janssen also objects that this Interrogatory improperly calls for a legal conclusion, which is not permitted by Federal Rule 33. *See Martin v. Evans*, No. 16-CV-11362-PBS, 2018 WL 10247394, at *3 (D. Mass. Feb. 6, 2018); *Iantosca v. Benistar Admin Servs., Inc.*, No. 08-11785-NMG, 2012 WL 220224, at *3 (D. Mass. Jan. 24, 2012).

Janssen further objects to this Interrogatory on the grounds that it has not received complete responses to its subpoenas to government agencies. Janssen objects to providing a response to this Interrogatory unless and until the government agencies complete their production of documents.

As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense. In answering Interrogatory No. 20, Janssen is not disclosing or intending to

imply anything about what legal advice may or may not have been provided. For avoidance of doubt, by providing the requested factual information and the identities of the individuals who provided privileged legal advice, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided, it is not asserting the advice of counsel defense and has not waived, and it has no intention of waiving, any applicable privilege.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

It is objectively reasonable to conclude that the provision of the IOI Support Services did not violate the Anti-Kickback Statute, and therefore there was no violation of the False Claims Act. At the time the product support services were provided, and through the present, Janssen had a good faith belief that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the Anti-Kickback Statute and False Claims Act. The legality of the programs is supported by the text of the Anti-Kickback Statute and False Claims Act, the relevant case law, and the publicly available guidance materials from HHS, which have consistently confirmed that product support services do not constitute unlawful kickbacks unless they provide substantial and independent value to the prescriber. *See* 68 Fed. Reg. 23,731, 23,735 (May 5, 2003); *see also, e.g.*, Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed.Reg. 79,202, 79,210 (Dec. 27, 2013). Moreover, the IOI Support Services at issue here were not an "inducement," and there can be no violation of the Anti-Kickback Statute without an "inducement." Furthermore, on multiple occasions, HHS-OIG has found that the AKS is not implicated by comparable programs and services. *See, e.g.*, OIG Advisory Opinions and judicial decisions cited in Janssen's Motion to Dismiss Relator's Second Amended Complaint ("Janssen's Motion to Dismiss"), ECF No. 59, at 6, 8–12.

Janssen further responds that its good faith and reasonable efforts to comply with the Anti-Kickback Statute and False Claims Act are supported by the robust practices and standards of its HCC department applicable to ABS engagement with physician practices. As stated in Janssen policy documents, the role of the HCC department was to "[o]versee and monitor[] the implementation of [a] compliance program" and "develop standards of conduct and policies and procedures that promote conformance to the company's compliance program." JANSSENBIO-037-00000270 at 277-282.

HCC members who reviewed the IOI Support Services at issue include Chris Zalesky (Director/Executive Director, Marketing Compliance (Centocor), April 1998–October 1999; Director, Regulatory Affairs (Janssen), October 1999–March 2002; Senior Director, Regulatory Affairs (Janssen), March 2002–May 2004; Executive Director, World Wide Office of Health Care Compliance and Policy, June 2004–March 2010; Vice President, Global Policy & Guidance, 2010–2016), Maripat Rhood (Manager, HCC, May 2001–July 2007), Michael Schoeck (Director, HCC and Privacy, October 2002–August 2008; Director, HCC, August 2008–December 2010), Edmund Greenidge (Director, HCC, 2005–October 2010), Gina Giordano (HCC Officer, June 2009–October 2015), John "Chip" Franz (HCC Officer, October 2010–August 2014), Angela Wood (HCC Officer, November 2010–June 2014), Roger Kung (HCC Officer, 2011–2012), Tom Cornely (HCC Officer, Immunology, April 2013–2016), Michele Blades (HCC Officer, March 2017–present), and Erin Parsons (HCC Officer, January 2015–November 2019).

Janssen has produced relevant and responsive HCC policies and training presentations, including policies related to Entertainment and Business Meals, the promotion of FDA-

Regulated Products, and Consulting and Product-Related Items and Services Provided to Customers, which are listed in Appendix A.

Janssen's good faith and reasonable efforts to comply with the Anti-Kickback Statute and False Claims Act are also supported by the existence and practices of the Promotional Review Committee. *See* Janssen's response to Interrogatory No. 3 for information concerning the role of, and persons with involvement in, the PRC, and the Standard Operating Procedures and PRC forms contained in Appendix B.

As explained in more detail below, Janssen's good faith belief that it complied with the Anti-Kickback Statute and False Claims Act is further supported by Janssen's disclosure of its IOI Support Services in connection with a significant federal government investigation that began as early as 2003 and ultimately resulted in the government's declination to intervene in at least two qui tam suits: *U.S. ex rel. Heineman v. J&J*, No. 2:05-cv-2633 (D.N.J.); *U.S. ex rel. Greer v. J&J d/b/a Centocor*, No. 07-cv-1660 (D. Minn.).

Between approximately 2003 and 2011, the Department of Justice ("DOJ") and OIG conducted an investigation that involved, among other topics, the IOI Support Services. On July 2, 2003, the U.S. Attorney's Office for the District of New Jersey issued a document request that included 40 requests for production. *See* JANSSENBIO-037-00001377. On February 11, 2005, the government followed up with 10 additional requests for production. *See* JANSSENBIO-037-00001373. In response to these requests, Janssen produced documents bates labeled JJDOJ0000001-0102780.

Additionally, on November 28, 2005, Janssen received additional document requests from the government. *See* JANSSENBIO-037-00001365. These document requests were focused on sales information and adverse effects of Remicade. *See id.* at Request Nos. 2-4, 7. In

response to these requests, Janssen produced documents bates labeled JJDOJ-CIV-000002-216610.

DOJ also requested, and Janssen produced, all documents produced by Janssen in the AWP MDL, totaling over 105,000 pages, in the summer of 2008.

Janssen has produced documents labeled JJDOJ0040284-0065635 in this litigation and intends to, at a minimum, produce responsive documents identified in the ranges labeled JJDOJ0080027-0082953 and JJDOJ0086213-0087503.

As part of this investigation, DOJ and OIG reviewed and analyzed the patient support services that Relator now claims are kickbacks. The government closed the investigation, and the DOJ and OIG did not take any action against Janssen, despite knowing about the IOI Support Services. Given the government's extensive knowledge of Janssen's IOI Support Services, and the fact that the government has not taken any action against Janssen, Janssen reasonably believed that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the AKS and FCA. Indeed, in many instances, the services Relator claims are kickbacks are either identical or substantially similar to the presentations that the government investigated. *Compare, e.g.*, JANSSENBIO-035-00010006 through JANSSENBIO-035-00010092 at JANSSENBIO-035-00010053 *with* JANSSENBIO-013-00005631; JANSSENBIO-035-00010006 through JANSSENBIO-035-00010092 at JANSSENBIO-035-00010018 *with* JANSSENBIO-017-00025032; JANSSENBIO-035-00008490 *with* JANSSENBIO-014-00002781. Thus, Relator cannot demonstrate falsity, scienter, intent, or materiality.

Witnesses with knowledge concerning this investigation are Joseph Braunreuther, Freddy Jimenez, and Chris Zalesky.

Janssen's good faith belief that it complied with the Anti-Kickback Statute and False Claims Act is further supported by the fact that Janssen disclosed and relied on its provision of IOI Support Services in its defense in the AWP MDL, including with live testimony at trial. Examples of such disclosures can be found on the AWP MDL docket at ECF Nos. 1326-7, 1325, 3289, 3288, 3397; *see also* Transcript of Bench Trial - Day Five. Witnesses with knowledge concerning this litigation are Joseph Braunreuther and John Hoffman.

Janssen's good faith belief that it complied with the Anti-Kickback Statute and False Claims Act is further reinforced by Relator Julie Long's admission that she believed these IOI Support Services were legal during the entirety of her thirteen-year tenure as a professional at Janssen. *See* Relator's Supplemental Objections and Responses to Janssen's Interrogatory Nos. 8–9. Relator Julie Long further indicated that no Janssen employee ever told her that they believed the IOI Support Services violated these statutes. *See id.*

Janssen's investigation is ongoing. Janssen expressly reserves the right to supplement, amend, and/or correct its response to Interrogatory No. 20 any time in light of any facts, documents, or other information that may subsequently come to light and/or for any other appropriate reason. Janssen's response to Interrogatory No. 20 shall not be deemed to constitute an admission or representation that any statement or characterization herein is complete.

INTERROGATORY NO. 22:

In Affirmative Defense No. 8 of your Answer to the Second Amended Complaint you contend that "any false claims that Janssen allegedly submitted or caused to be submitted and any false record or statement that Janssen allegedly made, used, or caused to be made or used to get a claim paid were not done knowingly." Set forth all facts, documents, and evidence that

support your contention and identify the witnesses who have knowledge concerning your contention.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 22:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory as untimely under the Court's order dated December 18, 2020, which required written discovery requests to be served by January 22, 2021.

Janssen further objects to Relator's Interrogatories as in violation of Local Rule 26.1(c) and the Court's order dated December 18, 2020, both of which limit each party to 25 interrogatories. Relator served 18 enumerated interrogatories on January 19, 2021, which Relator amended per Court order on May 14, 2021; 1 enumerated interrogatory on May 13, 2021; 14 enumerated interrogatories on May 19, 2021; and 3 enumerated interrogatories on January 3, 2022, bringing her total number of interrogatories to 36. When factoring in sub-parts of Relator's Interrogatories and Amended Interrogatories, which per the Federal Rules of Civil Procedure should be counted independently, Relator has served, and Defendant has responded to, at least 77 Interrogatories. When incorporating the subparts to Relator's Definitions and Instructions to her Interrogatories, Relator has served, and Defendant has responded to, over 600 Interrogatories.

Janssen further objects to this Interrogatory to the extent that it requests information protected by the attorney-client privilege, attorney work product protection, or any other applicable privilege or protection.

Janssen further objects that this Interrogatory is vague, ambiguous, overbroad, and unduly burdensome in its reference to "all facts, documents, and evidence." *See generally* Wright & Miller, Fed. Prac. & Proc. Civ. § 2167 (3d ed.) ("Contention interrogatories may be

held unduly broad if they ask in an undifferentiated way for 'all' facts or witnesses that support an opposing party's case."). Janssen also objects to this Interrogatory in its entirety as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence.

Janssen also objects to this Interrogatory on the ground that it is premature. As Relator has acknowledged in her own interrogatory responses, discovery is in the initial stages and remains ongoing. Consistent with Fed. R. Civ. P. 26 and 33, Janssen will suplement its response to this interrogatory as necessary.

Janssen further objects that the AKS and other statutes and regulations at issue in this matter speak for themselves. Janssen further objects that this Interrogatory improperly calls for a legal conclusion, which is not permitted by Federal Rule 33. *See Martin v. Evans*, No. 16-CV-11362-PBS, 2018 WL 10247394, at *3 (D. Mass. Feb. 6, 2018); *Iantosca v. Benistar Admin Servs., Inc.*, No. 08- 11785-NMG, 2012 WL 220224, at *3 (D. Mass. Jan. 24, 2012).

Janssen further objects to this Interrogatory on the grounds that it has not received complete responses to its subpoenas to government agencies. Janssen objects to providing a response to this Interrogatory unless and until the government agencies complete their production of documents.

Janssen further objects to this Interrogatory insofar as it implies the burden is on Janssen to prove that it did not act "knowingly." Relator bears the burden to prove that Janssen acted "knowingly." As Janssen noted in its Answer, "[s]ome of the defenses listed may not constitute affirmative defenses and are listed out of an abundance of caution. By listing a defense here, Janssen does not assume an obligation to prove the truth of the matter stated, and instead, some of these defenses may be stating matters that the Relator cannot prove or establish as a matter of

law or may relate to elements of Relator's claim that she cannot prove because the facts are otherwise." Janssen's Answer to Relator Julue Long's Second Amended Complaint, ECF No. 83, at p. 51 n.1.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

It is Relator's burden to establish that the IOI Support Services led to the "knowing" submission of allegedly false claims under the statutory requirements of the FCA and as that term has been defined by relevant case law, and Relator cannot meet this burden because she has no evidence to support her allegation that Janssen knowingly violated the Anti-Kickback Statute and False Claims Act.

The reasonableness of Janssen's interpretation of the governing statutes and regulations and its good faith belief that the IOI Support Services complied with the Anti-Kickback Statute and False Claims Act are addressed in Janssen's responses to Interrogatory Nos. 15 and 20.

Furthermore, there is no evidence that Janssen "knew" that there was a violation of the Anti-Kickback Statute, that any alleged violation of the AKS caused any provider to submit a claim to a federal healthcare provider, that any alleged claim was false, or that any alleged violation was material to the government. Indeed, in response to Janssen's Contention Interrogatory Nos. 13–15, Relator Julie Long has provided no evidence that Janssen knowingly did any of these things. *See* Relator's Supplemental Objections and Responses to Janssen's Interrogatory Nos. 13–15.

Janssen's investigation is ongoing. Janssen expressly reserves the right to supplement, amend, and/or correct its response to Interrogatory No. 22 any time in light of any facts, documents, or other information that may subsequently come to light and/or for any other

appropriate reason. Janssen's response to Interrogatory No. 22 shall not be deemed to constitute an admission or representation that any statement or characterization herein is complete.

VERIFICATION

I am the Vice President, Immunology Portfolio Strategy at Janssen Biotech, Inc. I am authorized to make this verification on behalf of Janssen Biotech, Inc. I have read Defendant's foregoing Supplemental Objections and Responses to Relator Julie Long's Interrogatory Nos. 3, 5, 7, 8, 9, 15, 20, and 22. I swear under penalty of perjury that the information provided is true and accurate to the best of my knowledge, information and belief.

Executed on March 23, 2023.

Brian Smith

AS TO OBJECTIONS AND RESPONSES:

Dated: March 23, 2023

s/ Jason C. Raofield

Jason C. Raofield (BBO No. 641744)
Ethan M. Posner (admitted *pro hac vice*)
Kristin M. Cobb (admitted *pro hac vice*)
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Attorneys for Defendant Janssen Biotech, Inc.

Appendix A
HCC SOPs and Trainings

JANSSENBIO-011-00008078	JANSSENBIO-011-00008347	JANSSENBIO-013-00010691
JANSSENBIO-013-00014696	JANSSENBIO-013-00015412	JANSSENBIO-013-00019244
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JANSSENBIO-015-00000072	JANSSENBIO-048-00002203	JANSSENBIO-048-00000591
JANSSENBIO-018-00001168	JANSSENBIO-018-00003439 to JANSSENBIO-018-00006046	JANSSENBIO-021-00004187 to JANSSENBIO-021-00004210
JANSSENBIO-018-00003439 to JANSSENBIO-018-00006046	JANSSENBIO-022-0000001 to JANSSENBIO-022-00000080	JANSSENBIO-024-00000001 to JANSSENBIO-024-00000087

Appendix B
PRC Approval Forms

JANSSENBIO-017-00023938	JANSSENBIO-017-00023983	JANSSENBIO-017-00024029
JANSSENBIO-017-00024028	JANSSENBIO-017-00024209	JANSSENBIO-017-00045687
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JANSSENBIO-030-00006487	JANSSENBIO-031-00002904	JANSSENBIO-031-00013884
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document has been served by electronic mail on March 23, 2023, to the following counsel of record:

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